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Dear Members of Congress:

Reason for Hope, the Veteran Mental Health Leadership Coalition (VMHLC), and the undersigned organizations are proud to support the Breakthrough Therapies Act introduced by Senators Cory Booker and Rand Paul.

The unfortunate reality of our nation's mental health crisis – while complex – highlights the limitations of effective pharmacologic treatments and therapies in our toolbox for stress and trauma-related concerns such as PTSD, depression, and suicidality. Indeed, as Tom Insel, our former Director of the National Institutes for Mental Health, noted: "It's a pretty safe bet in most of medicine that if you treat more people, death and disability drop. But when it comes to mental illness, there are more people getting more treatment than ever, yet death and disability continue to rise."[1]

The federal government should thus do everything possible to support (or at least not stand in the way of) urgently needed investigation of novel therapeutics with potential to offer relief and healing to individuals who have been failed by current treatments, especially those which can offer rapid and robust improvements. Mounting evidence suggests fast-acting therapeutics like MDMA and psilocybin – currently classified as Schedule I drugs under the Controlled Substances Act – have great potential to offer this level of healing to individuals suffering from a variety of mental health conditions.

[1] Healing: Our Path from Mental Illness to Mental Health, p. 19

Indeed, initial clinical trial results have been so promising that the Food and Drug Administration granted Breakthrough Therapy designations to both MDMA- and psilocybin-assisted therapies, meaning that they demonstrate substantial improvement over currently available treatments (for PTSD and depression, respectively).

Yet, because MDMA and psilocybin are currently classified as Schedule I drugs, it is nearly impossible to legally access these breakthrough therapies within the United States, including for patients who have exhausted available treatments and are at serious risk of suicide. Moreover, the Controlled Substances Act severely impedes and drives up the cost of even basic clinical research of MDMA, psilocybin, and other promising Schedule I psychedelic substances such as ibogaine and 5-MeO-DMT. Thus, we should not be surprised – but should be highly ashamed – that our Veterans are leaving the country they served to seek out these treatments where they can legally do so abroad.

Indeed, as recently noted in our written testimony for the House Veterans' Affairs Committee hearing on suicide prevention, in the last several years, members of the VMHLC have supported over 1,065 Veterans to receive psychedelic-assisted therapy outside our nation's borders.[2] We have worked with many of these Veterans who were not only saved from suicide, but also found a renewed sense of purpose, meaning, and connection to themselves, their families, and their communities after undergoing this form of treatment.[3] Beyond MDMA and psilocybin, many Veterans (particularly within the Special Operations Forces community) have been successfully treated with a combination therapy of ibogaine and 5-MeO-DMT, with a retrospective study reporting very large reductions in suicidal ideation, cognitive impairment, and symptoms of posttraumatic stress disorder, depression, and anxiety. A large majority of participants also rated the psychedelic experience as one of the most personally meaningful, spiritually significant, and psychologically insightful of their lives.[4]

2 https://docs.house.gov/meetings/VR/VR00/20220929/115166/HHRG-117-VR00-20220929-SD013.pdf

3 See, e.g., the Connecticut Public Health Committee testimony of Marcus and Amber Capone, co-founders of Veterans Exploring Treatment Solutions, Jesse Gould, founder of Heroic Hearts Project, and Allison Wilson, founder of the Hope Project, in support of Connecticut HB 5396, available at https://www.cga.ct.gov/asp/menu/CommDocTmyBillAllComm.asp?bill=HB-05396&doc_year=2022.

4 Davis AK, Averill LA, Sepeda ND, Barsuglia JP, Amoroso T. Psychedelic Treatment for Trauma-Related Psychological and Cognitive Impairment Among US Special Operations Forces Veterans. Chronic Stress. 2020;4. doi:10.1177/2470547020939564

Ultimately, psychedelic-assisted therapy provides a reason for hope for many people currently suffering – particularly those who have failed to find relief through other available options. So, how can we justify a regulatory system that actively suppresses this entire class of potential treatments, when:

- virtually every metric of our nation's mental health has regressed for several decades;
- we have seen minimal progress in new pharmacologic treatments, despite having only two FDA-approved medications for PTSD, which are slow acting and have significant limitations and side effects;
- estimated Veteran suicides range from 16 to as many as 44 per day, with male Veterans two-to-three times as likely to die by suicide than their civilian counterparts, and female Veterans six times as likely;
- for every death by suicide, an estimated more than 30 others attempt suicide (estimate based only on reported attempts, and many go unreported/untreated); and
- the devastating economic and societal costs of suicide are estimated at well over $69 billion annually?[5]

Put simply: the status quo cannot be justified. Thus, we urge members of Congress to support the Breakthrough Therapies Act, which removes certain burdensome federal regulations that impede research and development of – and ultimately access to – potentially lifesaving Schedule I drugs. Significantly, the Breakthrough Therapies Act enables DEA to transfer MDMA and psilocybin from Schedule I to Schedule II, which would help lower administrative barriers and costs for a potential phased roll-out of these breakthrough therapies via FDA-approved Expanded Access pilot programs.

5 https://docs.house.gov/meetings/VR/VR00/20220929/115166/HHRG-117-VR00-20220929-SD013.pdf

Utilizing this phased approach is a reasonable path forward both for states and the VA healthcare system, as it facilitates critical patient access, and training opportunities for providers in need of real-world treatment experience. Expanded Access pilot programs would also allow for treatment of a more diverse set of patients with complex comorbidities (who are otherwise not eligible for clinical trials) and would generate valuable real-world data to inform FDA safety policies and product labeling. Further, such programs can explore different treatment protocols – such as the use of group therapy and peer support specialists – that seek to find the optimal balance of safety, efficacy, affordability, and equitable access.

Responsibly ushering in this new paradigm of mental health care is a national imperative. Congress can and should help to achieve it by swiftly passing the Breakthrough Therapies Act before year-end. We hope to see overwhelming bipartisan support for this potentially life-saving legislation.

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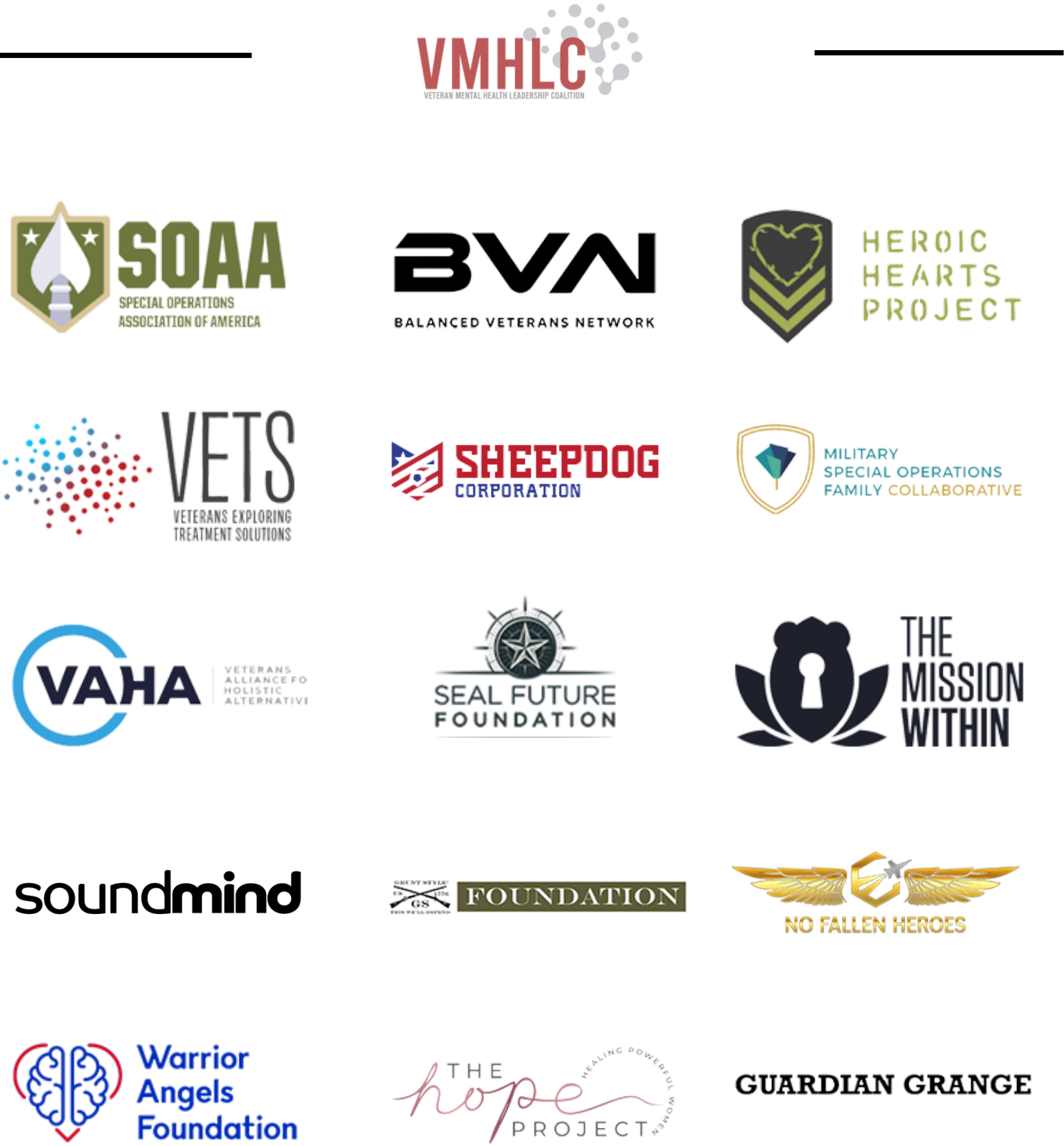
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